IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF DUANE PRIDDY, PH.D.

Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon"), submit this memorandum in support of their motion to exclude the opinions and testimony of Duane Priddy, Ph.D. The cases to which this motion applies are identified in Ex. A.

INTRODUCTION

Plaintiffs designated Dr. Duane Priddy, Ph.D., to offer general causation opinions regarding the alleged oxidative degradation of the Prolene polypropylene in pelvic mesh products manufactured by Ethicon, including TVT, TVT-O, TVT-Secur, TVT Abbrevo, TVT Exact, Gynemesh PS, Prolift, Prolift+M, and Prosima (collectively, "Ethicon mesh products").

In support of his general causation opinions, Dr. Priddy conducted Oxidative-Induction Time ("OIT") testing on ten samples of Prolene taken from pristine Ethicon mesh products in an effort to (i) assess the performance of the antioxidants in Prolene; (ii) predict how long it will take for Prolene to oxidize and degrade; and (iii) evaluate the relative oxidative stability of the Prolene samples. To do so, Dr. Priddy heated the mesh samples to 200° C in an environment of 100% nitrogen that was changed during the testing to 100% oxygen. Dr. Priddy then repeated the

OIT testing, although the atmosphere was changed from 100% nitrogen to ambient air during the second run.

After the OIT testing was complete, Dr. Priddy extracted the antioxidants from the samples using a methylene chloride solvent and sonication, and conducted gas chromatography-mass spectroscopy ("GC/MS") testing at temperatures of over 200° C in an attempt to quantify the relative antioxidant levels among the samples.

The Court should exclude Dr. Priddy's OIT and GC/MS testing as unreliable and irrelevant because his testing (i) has no correlation to the performance of Ethicon mesh products in the human body; (ii) produces uncertain and speculative results; (iii) was not conducted in accordance with a protocol; (iv) was performed without the use of a proper control; and (v) was not validated using statistical analysis.

In addition, Dr. Priddy offers various opinions regarding Ethicon's knowledge, state of mind, and corporate conduct. He also seeks to opine about clinical complications allegedly caused by the oxidative degradation of the Prolene in Ethicon mesh products. But Dr. Priddy is not qualified to offer such opinions, which the Court should exclude on that basis.

ARGUMENT

I. Legal Standard

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1–3, (S.D. W. Va. July 8, 2014).

II. Dr. Priddy's OIT Testing Is Unreliable and Irrelevant.

Dr. Priddy performed OIT testing on ten Ethicon mesh exemplars. *See* Ex. B, Priddy Report at 3–4, 11–13.[1] He conducted OIT testing to "compare the relative thermal oxidative stability" of the samples, and to "evaluate the performance of the antioxidant stabilizer in the Ethicon mesh samples and to predict the approximate time to oxidative degradation of the meshes[.]" Ex. B, Priddy Report at 3.[2] Dr. Priddy opined that "[b]ecause the degradation science of [polypropylene] has been well known for over 40 years, and the availability of accelerated laboratory aging technology allowing rapid assessment of the rate of material degradation, it is clear that Ethicon meshes manufactured using [polypropylene] cannot survive long term use as a reinforcing medical implant." Ex. B, Priddy Report at 3–4.

Dr. Priddy then sought to correlate the level of antioxidants in the mesh samples with his OIT test results using GC/MS. *Id.* at 13. To do so, after the completion of the OIT testing, Dr. Priddy directed Mr. Johnson to extract the antioxidants present in the samples using "methylene chloride solvent" and sonication. *Id.* Mr. Johnson then analyzed the extracts using GC/MS to identify the relative amounts of antioxidants present in the samples. *Id.* Based on this testing, Dr. Priddy concluded that there was significant variation in the amount of antioxidants in the samples, and this variation correlated with his OIT test results. *Id.*

[1] Dr. Priddy testified that the OIT and gas chromatography—mass spectroscopy testing on which he bases his opinions was actually performed by Mr. Steve Johnson. Ex. C, Priddy 3/8/16 Dep. Tr. 82:1–5.

[2] Dr. Priddy's Report explains that he was measuring the "incipient surface oxidation time (ISOT)" through his testing. Yet, Dr. Priddy admitted at deposition that ISOT is not a recognized standard; rather, ISOT comes from "nowhere," "is my own acronym," and is something he made up. Ex. C, Priddy 3/8/16 Dep. Tr. 65:18–23; 66:14–67:1.

A. Dr. Priddy's Testing Does Not Replicate the *In Vivo* Environment in Which Ethicon Mesh Products Are Used.

Dr. Priddy's testing should be excluded as unreliable in this case because it bears no relationship to what occurs in the human body. This Court has repeatedly excluded experts' *ex vivo* testing that does not replicate the human physiological environment. *See Frankum v. Boston Sci. Corp.*, No. 2:12-cv-0904, 2015 WL 1976952, at *15 (S.D. W. Va. May 1, 2015); *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at **8–9 (S.D. W. Va. Sept. 29, 2014).

1. Dr. Priddy's OIT tests were conducted under conditions vastly different than the human body.

In this case, Dr. Priddy's OIT testing consisted of heating mesh samples to 200° C, then exposing the samples to different atmospheric environments: (i) 100% nitrogen that was changed during the test to 100% oxygen; and (ii) 100% nitrogen that was changed to ambient air. Ex. B, Priddy Report at 12; Ex. C., Priddy 3/8/16 Dep. Tr. 36:10–15. Although Dr. Priddy was unable to provide details regarding the methodology used in the GC/MS testing, he testified that "it was [conducted] at over 200 degrees." *Id.* at 91:23–92:10.

As Dr. Priddy admitted at deposition, these conditions far exceed anything ever encountered in the human body. *Id.* at 46:5–17. Specifically, Dr. Priddy testified that the 200° C temperature used in his testing is equivalent to about 392° F, which is approximately 300° F above the normal temperature of the human body. *Id.* at 42:15–21; *see also id.* at 48:16–20 (testifying that the intended use temperature of Ethicon mesh products is 37° C or 98.6° F). Dr. Priddy also acknowledged that the *in vivo* environment would never involve concentrations of 100% nitrogen or 100% oxygen. *Id.* at 46:8–17. Although Dr. Priddy contends that the human body contains oxidizing species, *id.* at 46:15–16, he does not know the concentrations of those agents in the human body, *id.* at 70:14–71:4.

Despite his recognition of significant disparities between the conditions of his tests and the human body, Dr. Priddy made no effort in his Report or deposition to compare the environments used in his testing to the human body. Nor did he conduct any of the real-world testing that he testified are necessary to validate the results of any accelerated aging test. *See id.* at 44:11–17; 58:7–10. Absent a scientifically legitimate correlation to the human body, it cannot be said that Dr. Priddy's testing is reliable or that it would assist the trier of fact.

2. Dr. Priddy Tested Samples with Different Physical Structures and Properties than the Prolene Used in Ethicon Mesh Products.

By testing at 200° C, Dr. Priddy ran tests on mesh samples with radically different structures and physical properties than the Prolene in Ethicon mesh products used in patients. Dr. Priddy admitted at deposition that the study he relied on for using heat aging tests explained that "if temperatures are used which are considerably higher than the ones the material is exposed to under normal circumstances, the danger exists of introducing new degradation reactions." *See* Ex. C, Priddy 3/8/16 Dep. Tr. 62:2–16; *see also* Ex. D, E. de la Rie, *Polymer Stabilizers: A Survey with Reference to Possible Applications in the Conservation Field*, 33 Studies in Conservation 9–22 (1988).[3]

As discussed above, although the intended use temperature of Ethicon mesh products is 37° C, Ex. C, Priddy 3/8/16 Dep. Tr. 48:16–20, all of Dr. Priddy's tests were conducted at 200° C, Ex. B, Priddy Report at 12. Furthermore, Dr. Priddy acknowledged that the melting point of Prolene is 165° C, Ex. C, Priddy 3/8/16 Dep. Tr. 43:3–4, and that while his OIT testing did not require melted samples, all of his OIT testing was conducted on molten Prolene, *id.* at 34:19–35:3.

[3] Dr. Priddy claimed to account for the de la Rie study by stating that his tests were "only a rough approximation" that "has to be validated with actual real-time studies." *See* Ex. C, Priddy 3/8/16 Dep. Tr. 62:20–63:2. But Dr. Priddy admitted that he never conducted those real-time studies to validate his work. *Id.* at 58:7–10.

Thus, despite knowing that heat-based aging tests could "introduce new degradation reactions"—an issue he failed to investigate—all of Dr. Priddy's tests involved the examination of molten polymers with no effort to show that the molten Prolene behaves the same as the solid-state Prolene used in the human body. Such disparities introduce substantial uncertainties in terms of oxidation and degradation rates that Dr. Priddy made no effort to address.

3. The Exclusion of Dr. Priddy's Opinions is Consistent With This Court's Decisions.

This Court's opinion regarding an expert offering a similar opinion in pelvic mesh litigation is instructive. In *Frankum*, Dr. Jimmy Mays sought to opine that the pelvic mesh at issue was subject to oxidation and degradation based on his thermogravimetric analysis ("TGA") testing, a common test for examining the thermo-oxidative stability of polymers. *See Frankum*, 2015 WL 1976952, at **14–15. Similar to Dr. Priddy's OIT testing in this case, Dr. May's TGA involved exposing the mesh samples to "temperatures well over 200 degrees Celsius when the human body is only approximately 37 degrees Celsius." *Id.* at *15. Plaintiffs in *Frankum* argued that "TGA is 'not intended to mimic the in vivo environment,' but instead 'is used as a model and provides predictive information that is particularly useful for product lifetime assessments.'" *Id.* (citations omitted).

In excluding Dr. Mays's opinions, the Court found that he "produced certain results while testing polypropylene at very high temperatures," and "then somehow concludes that the same results will occur inside the human body at much lower temperatures, without providing any explanation or support for his opinion." *Id.* (concluding that "Dr. Mays has failed to connect his TGA results to the pertinent inquiry, which is whether the [mesh] degrades inside the human body."). The Court's decision regarding Dr. Priddy's opinions in this case should be no different.

B. The Court Should Exclude Dr. Priddy's OIT Testing As Unreliable and Irrelevant.

1. By Its Own Terms, Dr. Priddy's OIT Testing is Unreliable and Speculative as It Relates to Ethicon Mesh Products.

Although Dr. Priddy purportedly followed ASTM 3895 as the protocol for his testing, the provisions of the protocol demonstrate that Dr. Priddy's testing is unreliable and speculative in this case. Ex. E, ASTM 3895-14.[4] As an initial matter, the text of ASTM 3895 reveals that it is not appropriate for making assessments regarding materials exposed to *in vivo* conditions. Specifically, the protocol states that the "test has the potential to be used as a quality control measure to monitor the stabilization level in formulated resin as received from a supplier, prior to extrusion." *Id.* at § 5.1. Thus, by its own terms, OIT testing using ASTM 3895 is intended to assess the stabilization of polymeric resins before the resin is extruded into fibers—not finished products.

In addition, Note 3 to ASTM 3895 states that no "definitve relationships [have] been established for comparing OIT values on field samples to those on unused products, hence the use of such values for determining life expectancy is uncertain and subjective." Ex. E, ASTM-3895-14 at 2. Thus, according to the terms of the protocol Dr. Priddy used in his testing, there is no scientifically legitimate relationship between Dr. Priddy's test results and Ethicon mesh products that have been implanted in patients. Indeed, Dr. Priddy admitted at deposition that life

[4] Although Dr. Priddy testified that he likely used an older version of ASTM 3895, he could not identify any differences in the two versions. *See* Ex. C, Priddy 3/8/16 Dep. Tr. 27:4–24. Furthermore, a review of the summary of changes in ASTM 3895 -14 demonstrates that none of the changes affected any aspect of the protocol addressed in this motion. *See* Ex. E, ASTM 3895-14 at 8.

expectancy preditions derived from this testing method are "uncertain" and "subjective." *See* Ex. C, Priddy 3/8/16 Dep. Tr. 50:23–51:4; 51:14-24.[5]

ASTM 3895's Note 7 explains that the "material composition of the specimen holder can influence the OIT test result significantly[.]" *See* Ex. E, ASTM 2895-14 at 7. Yet, Dr. Priddy admitted at deposition that he did not take any steps to determine whether the specimen holder affected the results of his testing on Prolene. *See* Ex. C, Priddy 3/8/16 Dep. Tr. 54:17–55:14. Although Dr. Priddy claimed that such validations had been conducted on "past projects," *id.* at 55:8–14, he conceded that he had never conducted any type of degradation testing or analysis on Prolene prior to this case, *id.* at 114:13–18. Indeed, Dr. Priddy could not even identify the composition of the specimen holder used in his tests. *Id.* at 54:5–9.

Dr. Priddy chose to rely on this testing for his opinions in this litigation despite the fact that the protocol itself cautions that OIT measurement "can be misleading." *See* Ex. E, ASTM 3895, Note 2 at 2.[6] The Court should not permit Dr. Priddy to offer opinions at trial based on

[5] In addressing Note 3's caution that comparing "field samples" to "unused products" is unreliable, Dr. Priddy testified that the "field sample" in his testing is the "virgin, unused implant," as opposed to a mesh explant. *See* Ex. C, Priddy 3/8/16 Dep. Tr. 48:24–49:18. Dr. Priddy's failure to distinguish between pristine and used samples shows that he did not grasp the significance of Note 3's warning regarding the lack of reliability of life expectancy predictions.

[6] Dr. Priddy's testimony shows that he did not fully understand the significance of Note 2. When pressed at deposition to explain the meaning of "misleading" in the context of Note 2, Dr. Priddy testified that "it would be misleading for me to say that one [polypropylene] is better than the other" if he examined "two different polypropylenes with two different stabilizer packages . . . and I run an OIT and get different values[.]" *See* Ex. C, Priddy 3/8/16 Dep. Tr. 45:7–22. Dr. Priddy clearly missed the point of Note 2's warning that OIT testing can be misleading, because Note 4 directly addresses the point Dr. Priddy raised at deposition. *See* Ex. E, ASTM 3895, Note 4 at 2 (explaining that "OIT test is a function of a particular compound's stabilizer system and should be be used as a basis of comparison between formulations that might contain different resins, stabilizers, or additive packages, or all of these.").

methods that—as described by Dr. Priddy's protocol—can produce "uncertain," "subjective," and "misleading" results.

2. Dr. Priddy Failed to Follow His OIT Testing Protocol.

Although Dr. Priddy claims that he "did not deviate from the protocol listed in" ASTM 3895, *see* Ex. B, Priddy Report at 3, his deposition testimony demonstrates that he failed to follow the protocol's sample preparation procedures. Section 9 of ASTM 3895 provides a recommended sample preparation procedure in order to ensure "consistent sample morphology and weight." *See* Ex. E, ASTM 3895 § 9.1 at 2. Yet, Dr. Priddy admitted that his test samples were not compressed or molded into a sheet format in accordance with ASTM section 9.1. *See* Ex. C, Priddy 3/8/16 Dep. Tr. 36:2–4. Notably, Dr. Priddy failed to record the sample preparation process in his Report and was unable to identify the average thickness of the samples, (*see id.* at 35:12–36:1; 38:15–21), thereby preventing an assessment of the methodology used in his testing.

Dr. Priddy did not offer any scientific basis for his deviation from the protocol. He claimed that (i) the sample preparation process was merely "recommended"; (ii) adherence to the process would have "affected the results negatively" by adding another "heat history"; and, (iii) he "wanted to have the samples tested in their original use shape as monofilaments." *Id.* at 36:2–9; 37:16–38:3. But he made no effort to determine what effect, if any, compliance with the sample preparation protocol would have had on his test results. In addition, Dr. Priddy's rationale rings hollow given that all of the samples used in Dr. Priddy's testing were molten by the time the analysis began. Finally, the absence of a mechanism to ensure that the samples in Dr. Priddy's testing were uniform draws into question the "wide differences" he observed in his test results.

As this Court has explained, "[v]igorous adherence to protocols and controls are the hallmarks of 'good science.'" *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Oct. 17, 2014). Dr. Priddy's failure to follow his protocol in his testing further evidences the lack of reliability of his opinions. The Court should preclude Dr. Priddy from testifying on this basis.

C. Dr. Priddy Failed to Use a Control in His Testing.

Dr. Priddy and Mr. Johnson's testing is also unreliable because they failed to use proper controls. As an initial matter, nothing in Dr. Priddy's Report or deposition suggests that Mr. Johnson used a control when conducting his OIT testing. For this reason, Dr. Priddy cannot confirm that the methodology used in his OIT testing did not introduce error into his results.

Although Dr. Priddy claims that Mr. Johnson used a control for the GC/MS testing, Dr. Priddy's testimony demonstrates that Mr. Johnson merely used an "internal standard" to determine if the "equipment is operating." *See* Ex. C, Priddy 3/8/16 Dep. Tr. 84:2–13. But Dr. Priddy made no effort to control for the effects of his testing methodology.

For example, Dr. Priddy and Mr. Johnson did not perform the removal process on a sample of pure polypropylene—*i.e.*, a sample not containing antioxidants. Thus, Dr. Priddy cannot confirm that the use of methylene chloride and sonication in the extraction process did not introduce error by affecting the polypropylene component of Prolene. Likewise, because they failed to run a sample of pristine Prolene through the extraction process, Dr. Priddy cannot confirm that the prior OIT testing process itself did not confound the GC/MS results. Indeed, Dr. Priddy and Mr. Johnson failed to use such controls even though the GC/MS testing failed to

detect one of the antioxidants used in Prolene unless the test conditions were altered. *See* Ex. B, Priddy Report at 8; Ex. C, Priddy 3/8/16 Dep. Tr. 87:12–88:14.[7]

Absent such controls, Dr. Priddy cannot determine if there is any potential rate of error associated with attempting to extract antioxidants by soaking the samples in a methylene chloride solvent and applying sonication. *See, e.g., Cooper v. Smith & Newphew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (observing that "whether a technique has a high known or potential rate of error and whether there are standards controlling its operation" is a factor guiding a district court's *Daubert* inquiry); *see also Sanchez*, 2014 WL 4851989, at *28 ("Vigorous adherence to protocols and controls are the hallmarks of 'good science.'").

D. Dr. Priddy Lacks a Sufficient Understanding of His Own Testing.

Dr. Priddy testified that all of the testing on which he bases his opinions was performed by a technician, Mr. Steve Johnson. *See* Ex. C, Priddy 3/8/16 Dep. Tr. 81:18–82:12. Although an expert can rely on testing performed by others at his direction, such reliance does not obviate Federal Rule of Evidence 702's requirement that expert testimony consist of "scientific, technical or specialized knowledge" that will assist the trier of fact, and "based upon sufficient facts or data" and "the product of reliable principles and methods" which has been reliably applied "to the facts of the case." *See Edwards*, 2014 WL 3361923, at *1.

In this case, it is not possible to determine whether Dr. Priddy's opinions are consistent with Rule 702 because he was unable to answer numerous questions regarding the methodology employed by Mr. Johnson. For instance, Dr. Priddy failed to provide information in his Report or deposition regarding the sample preparation process for the OIT testing. *See* Ex. C, Priddy 3/8/16

[7] Dr. Priddy failed to note in his Report that he and Mr. Johnson ran the test under different conditions; rather, the Report states only that "[m]y testing in this case [GC/MS] did not detect the presense of any [] additive other than Santonox R." *See* Ex. B, Priddy Report at 8. Nor did Dr. Priddy explain if this additional testing under different conditions altered the GC/MS results for the other additives.

Dep. Tr. 35:12–22. He did not know the standard operating procedure he claims Mr. Johnson followed in conducting the GC/MS testing. *Id.* at 82:14–83:5. Dr. Priddy could not identify the samples on which Mr. Johnson performed GC/MS testing. *Id.* at 91:15–22. Nor could Dr. Priddy specify the temperature at which the GC/MS testing was conducted, or the quantity of solvent that Mr. Johnson used in the additive extraction process. *Id.* at 92:6–10; 92:18–21.

At deposition, Dr. Priddy repeatedly deflected questions regarding the testing by pointing to a lab report purportedly provided to him by Mr. Johnson. *See, e.g.*, Ex. C, Priddy 3/8/16 Dep. Tr. 53:3–21; 82:14–83:5; 84:21–85:13; 99:3–22. But Dr. Priddy failed to produce a copy of this lab book to Ethicon.

Given the absence of information regarding the methodology used in his testing—and Dr. Priddy's inability to provide such information—it cannot be said that his opinions are consistent with Rule 702. Accordingly, the Court should preclude Dr. Priddy from testifying at trial.

E. Dr. Priddy Failed to Provide Statistical Analysis of His Test Data.

Dr. Priddy claims that he validated his test results using statistical analyses to correlate the OIT data with the GC/MS data regarding the amount of antioxidants in the mesh samples. *See* Ex. C, Priddy 3/8/16 Dep. Tr. 39:21–40:7. Yet, Dr. Priddy's Report contains no such statistical analysis. When pressed to explain his failure to include these alleged statistical analyses in his Report, Dr. Priddy stated merely that he "[j]ust didn't include it." *Id.* at 39:14–20.

Dr. Priddy asks the Court to take his word for it that he conducted statistical analysis on his test results, and that his analysis validated those test results. But "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

III. The Court Should Preclude Dr. Priddy From Testifying About Issues Beyond His Qualifications and Which Do Not Assist the Trier of Fact.

A. Dr. Priddy's Opinions Regarding Ethicon's Alleged Knowledge, State of Mind, and Corporate Conduct Do Not Assist the Trier of Fact.

In his Report, Dr. Priddy offers several opinions regarding Ethicon's alleged knowledge regarding the alleged oxidation and degradation of polypropylene. Specifically, Dr. Priddy states that "Ethicon knew, or should have known, that this process of degradation affects the plastic's integrity from the beginning and can be predicted." *See* Ex. B, Priddy Report at 4. Similarly, Dr. Priddy asserts in his Report that "[i]t is my expert opinion within a reasonable degree of scientific certainty that Ethicon knew or should have known that PP was not an appropriate material for use in permanent meical implants of transvaginal mesh." *Id.* at 14.

Dr. Priddy also states that "Ethicon's failure to [test Ethicon mesh products] deviates from the standards of a reasonable company and in this case jeopardized the health of the women receiving their products." *Id.*

This Court has repeatedly held that a corporate defendant's "knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *See, e.g., In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013). The Court should preclude Dr. Priddy from testifying about Ethicon's alleged knowledge, state of mind, or corporate conduct for this reason alone.

In addition, Dr. Priddy is not qualified to opine about Ethicon's corporate knowledge and conduct. Dr. Priddy is a chemical engineer. His resume does "not include knowledge or even experience in the manner in which corporations and the [medical device] marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and

influenced by shareholders or public opinion." *In re Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at 9 (E.D. Pa. June 20, 2000). Dr. Priddy is thus unqualified to offer any opinions concerning Ethicon's corporate conduct.

B. Dr. Priddy is Unqualified to Opine that the Alleged Degradation of Prolene in Ethicon Mesh Products Causes Clinical Complications.

Although Dr. Priddy seeks to inform the jury that "Ethicon's failure to [perform tests to determine whether its mesh would withstand permanent implantation in the body] . . . jeopardized the health of the women receiving their products," *see* Ex. B, Priddy Report at 14, he is not qualified by his knowledge, skill, experience, training, or education to opine that any act or omission by Ethicon caused a clinical complication in patients with Ethicon mesh products.

Dr. Priddy is not a medical doctor. *See* Ex. C, Priddy 3/8/16 Dep. Tr. 20:9–14. Thus, he lacks the qualifications necessary to offer opinions regarding clinical complications. Indeed, Dr. Priddy recognized as much at his deposition, admitting that "since I'm not a medical doctor, I can't equate the clinical" significance of his degradation opinions. *Id.* at 123:9–12. Dr. Priddy's lack of qualifications to offer opinions regarding the clinical complications allegedly caused by degradation is, by itself, a sufficient basis for the Court to exclude his testimony on these issues. *See, e.g., Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *7 (S.D. W. Va. July 8, 2011) (excluding expert testimony that went "beyond the experts' qualifications"); *see also Johnson & Johnson v. Batiste*, 2015 6751063, at *6, *9 (Tex. App.—Dallas Nov. 5, 2015, pet. pending) (concluding that evidence of degradation is legally insufficient where plaintiffs' experts could not identify testing establishing the clinical consequences of any alleged degradation).

CONCLUSION

For the foregoing reasons, Ethicon requests that the Court exclude the opinion testimony of Dr. Priddy, and grant such other and further relief as the Court deems proper under the circumstances.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 20, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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